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## ISO 9001 readiness

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**Goal of the module:** Readiness for implementation, certification, maintenance and improvement of your quality management system (ISO 9001) so as to be able to:

- increase the satisfaction of stakeholders
- improve economic and financial results
- demonstrate conformity to customer, statutory and regulatory requirements

## 1 Quality approach

### 1.1 Background

The evolution of the quality concept and the standards of quality management systems (Quality Management System = QMS) in the industrial countries in the 20<sup>th</sup> century can be summarised as:

- quality control (till the 1980s) – quality practices, customers are (or seem) satisfied
- quality assurance (the 1990s) – the system is defined and implemented
- quality management (ISO 9000: 2000) – the system is controlled and its efficiency is improved

The technical committee "Management and quality assurance" (ISO/TC 176) within the ISO (International Organization for Standardization) was created in 1980. ISO itself was created in 1947.

The ISO 9000 standards (see figure 1-1) have appeared in:

- 1987: ISO 9000 first edition: ISO 9001; ISO 9002; ISO 9003; ISO 9004
- 1994: ISO 9000 first revision: ISO 9001; ISO 9002; ISO 9003; ISO 9004 – more understandable, customer focus better defined, preventive actions added
- 2000: ISO 9000 second revision: ISO 9000; ISO 9001; ISO 9004 – simplified structure (8 clauses), priority to process approach and customer satisfaction
- 2008: third revision (fourth edition of ISO 9001): clarification of the requirements (no new requirement), better alignment with ISO 14 001

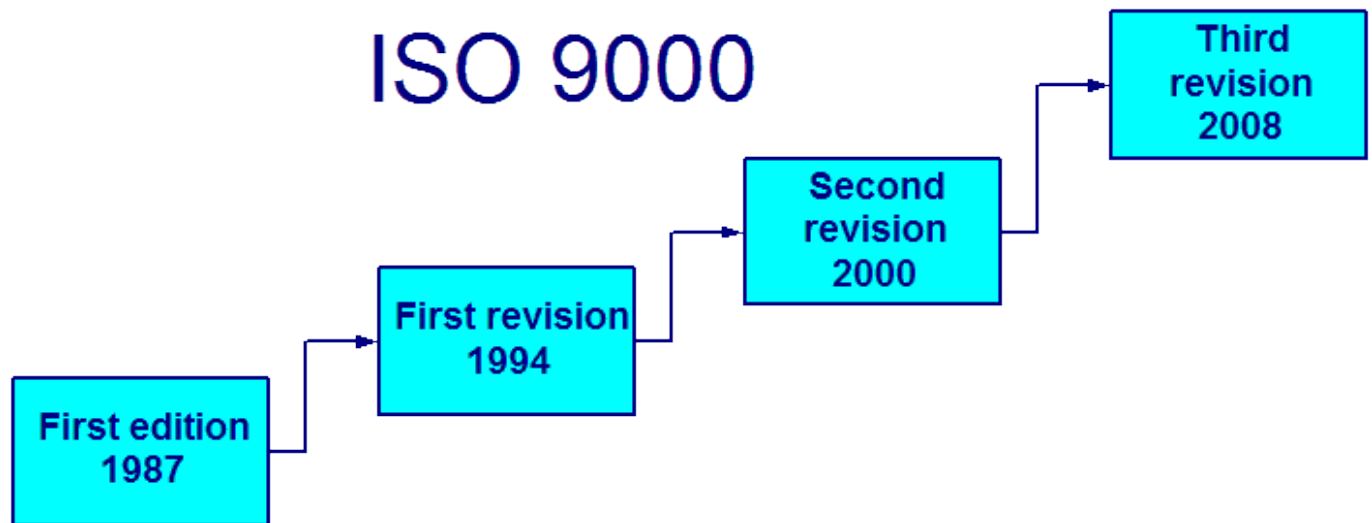


Figure 1-1. The first edition and revisions of ISO 9000

The new version of the ISO 9001 standard has been published in November 2008. In 2005 the ISO 9000 standard was updated.

The ISO standards (more than 18 000) are used in countless fields and are recognized all over the world.

### 1.2 Scope

The ISO 9001 standard (**Quality management systems - Requirements**) is generic as it can be applied to any organization, without limitations about size, activity or type. It is an international standard which allows certification by accredited organizations.

Some requirements can be excluded in some specific cases. This is possible when these exclusions:

- are limited to one (some) requirement (s) of clause 7 of ISO 9001 : Product realization
- do not affect in any case product conformity linked to:
  - customer requirements
  - applicable regulation requirements
- do not release the organization of its responsibilities
- are justified in the quality manual

### 1.3 Principles and steps

#### **Quality is anything that can be improved. Masaaki Imai**

Quality approach is a state of mind which starts with top management as a priority strategic decision and extends to all employees. Top management defines the quality policy which determines the quality objectives, themselves applicable to all activities. The tool used to achieve the objectives is the quality system. The prevention concept is generalised.

The purpose of a Quality Management System is to increase the satisfaction of customers (both external and internal) by meeting their needs and expectations through permanent improvement of the effectiveness of the processes.

Quality is almost free when the customer is satisfied: he remains loyal to us. It's only when the customer is not fully satisfied that quality becomes very expensive to us: sooner or later the customer will go to a competitor.

#### **Quality stays long after the price has been forgotten**

The eight quality management principles (cf. figure 1-2) will help us achieve sustained success (ISO 9000, subclause 0.2 and ISO 9004, Annex B).